UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,257	06/06/2001	Robert Hans Meloen	3516.2US	6928

24247 7590 03/04/2004

TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,257	MELOEN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The maintenance fee due by four years after the issue date of U.S. Patent No. 5,885,966 has been paid, and therefore the reissue procedures are available for this patent. See MPEP 1415.01.

2. The Assent Of Assignee filed January 16, 2004 is approved.

3. The executed Offer To Surrender Patent form filed on January 16, 2004 is approved.

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

4. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,885,966, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

5. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The declaration filed January 16, 2004 incorrectly refers to an unrelated patent. See page 2 of the declaration, second full paragraph.

Claims 1-15 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

7. The claim for priority inserted at the beginning of column 1 of the specification is objected to because: (1) It does not use appropriate language for a claim for priority under 35 U.S.C. 120. The claim does not set forth the relationship, e.g., continuation, divisional, or continuation-in-part, between the PCT application and the U.S. patent applications. (2) U.S. Patent Application Serial No. 08/477,013 is incorrect, and should instead be 08/476,013 (see, e.g., the reissue declaration filed June 6, 2001). (3) The status of the U.S. patent applications should be updated. Correction is required.

No amendment to the specification was found in Applicants' response filed January 16, 2004. Specification amendments are not mentioned or listed at page 1 of Applicants' response. Accordingly, this objection is maintained.

8. The amendment format of instant claims 3, 9, 11, 13, and 14 is incorrect. Deletions in reissue claims with respect to the text of the original patent claims are shown using brackets, not by strikethrough. See 37 CFR 1.173(b)(2) and (d)(1). Amendment format in a reissue application, governed by 37 CFR 1.173, is different than amendment format in a normal utility application, which is governed by 37 CFR 1.121. Correction is required.

9. Claims 5, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5, line 4, indicates that a cysteine is placed before the

glutamic acid at position 1 in LHRH. However, the sequences at claim 5, lines 2 and 3, do not show a glutamic acid at a position corresponding to position 1 of LHRH. Instead, the glutamic acid residue in LHRH has been replaced with a glutamine. Further, glutamic acid is not normally present at position 1 of LHRH; rather, pyroglutamic acid is the amino acid residue which is present at position 1 of naturally-occurring LHRH. At claim 5, line 7, "D-glycine" is indefinite because glycine does not have a D or L form. Claim 9 is indefinite because it is not clear how a peptide can comprise a mild adjuvant. A peptide can be combined with a mild adjuvant, or a composition comprising a peptide can additionally comprise a mild adjuvant. However, a mild adjuvant is not a chemical substituent which can be attached to a peptide. Claim 10 refers to a "composition in accordance with claim 9". However, claim 9 is now drawn to a peptide, not a composition.

10. Claims 2-5 are objected to because of the following informalities: SEQ ID NOS need to be inserted after the amino acid sequences recited in claims 2, 4, and 5. See 37 CFR 1.821(d). The SEQ ID NOS which were inserted into the claims by the preliminary amendments filed July 9, 2002 and June 6, 2003 were omitted from the listing of claims filed January 16, 2004. At claim 2, line 1, the word "an" was changed to "and" without appropriate marking under 37 CFR 1.173(b). The word should be changed back to "an". At claim 3, line 5, "an" should be changed to "a". In claims 4 and 5, the residue numbers for the upper sequences are misaligned. At claim 5, line 7, "D-lysine" has been changed to "D-glycine" without appropriate marking under 37 CFR 1.173(b). "D-glycine" needs to be changed back to "D-lysine". Appropriate correction is required.

11. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 3 requires at least two contiguous LHRH decapeptide sequences to be present in the peptide. However, dependent claim 5 does not comprise two such sequences because it replaces the pyroglutamic acid residue which is present at position 1 in LHRH (see, e.g., column 1, lines 19-27) with glutamine.

12. The terminal disclaimer filed January 16, 2004 has been approved and overcomes the obviousness-type double patenting rejection set forth in paragraph 10 of the previous Office action.

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 1 and 6-15 are rejected under 35 U.S.C. 103(a) as being obvious over Potter et al (U.S. Patent No. 5,723,129) in view of the GB Patent 2,228,262 or the GB Patent 2,196,969. Potter et al teach chimeric proteins comprising a leukotoxin fused to GnRH multimers. The GnRH peptides which form the multimers can be joined with a terminus to terminus linkage. The chimeric proteins can optionally be linked to a secondary carrier such as KLH and ovalbumin, and can optionally be combined with adjuvants such as oils. The chimeric proteins are used to vaccinate animals, such as to prevent boar taint, i.e. to immunocastrate pigs. Effective amounts range from 1 μg to 1 mg. See, e.g., the Abstract; column 5, lines 34-57; column 10, line 55 - column 11, line 23; column 14, lines 17-49; column 15, lines 39-45; column 16, lines 48-51; and claims 1 and 5. Potter et al teach the use of GnRH polypeptides which differ

in sequence from naturally occurring GnRH but which still retain the ability to elicit formation of antibodies that cross react with naturally occurring GnRH, but do not teach the use of specific GnRH polypeptides in which the residue at position 6 is a D-amino acid. The GB Patent '262 teaches GnRH analogs in which residue 6 is D-lysine. The analogs can be used to raise cross reacting antibodies, but have the advantage of being less susceptible to degradation by proteolytic enzymes present in vivo. See, e.g., the Abstract and page 10, lines 5-10. The GB Patent '969 teaches GnRH analogs in which residue 6 is a D-amino acid. The analogs can be used to raise cross reacting antibodies, but have the advantage of improved stability to degradation in vivo. See, e.g., the Abstract and page 2, lines 11-19. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the chimeric proteins of Potter et al in which the amino acids corresponding to residue 6 of GnRH are D-amino acids such as D-lysine, because such GnRH analogs are generically encompassed by Potter et al and because the British Patent '262 and the British Patent '969 suggest that such modified chimeric proteins would still be immunogenic but would have the additional advantage of being less susceptible to degradation by proteolytic enzymes present in vivo.

15. Applicant's arguments filed January 16, 2004 have been fully considered but they are not persuasive.

Applicants' claim amendments filed January 16, 2004 were not accompanied by a statement of status and support as required by 37 CFR 1.173(c). Further, Applicants' claim amendments filed January 16, 2004 made changes with respect to the original text of the patent claims which changes were not marked in accordance with 37 CFR 1.173(b). See paragraph 10 above. Finally, Applicants' claim amendments omitted previous amendments made to the claims

without any indication as to whether or not the omissions were intentional or not. Any future amendments to the claims should be carefully reviewed in order to ensure compliance with the reissue amendment rules and in order to ensure that the claims accurately reflect changes made to the claims during prosecution.

The objection to claim 5 under 37 CFR 1.75(c) set forth in paragraph 9 of the previous Office action is maintained. Rewriting claim 3 in independent form does not affect this objection. Further, inserting text which indicates that a cysteine is placed before the position 1 of LHRH does not resolve the conflict between the structure of claim 5, in which contiguous LHRH decapeptide sequences are not present, and the requirement for contiguous sequences set forth in independent claim 3. Finally, it should be noted, it is not clear what the inserted text in claim 5, even in corrected form, would add to the structure already recited in claim 5. The structure already explicitly requires a cysteine residues to be present before the QHWSY*LRPG sequence.

The obviousness rejections based upon the GB Patent 2,228,262 as the primary reference are withdrawn. Applicants have amended the claims to require that the contiguous LHRH sequences be joined with a terminus to terminus linkage. This excludes the dimers of the GB Patent '262, in which the LHRH sequences are linked through the sidechains of internal residues.

The obviousness rejection over Potter et al (U.S. Patent No. 5,723,129) in view of the GB Patent 2,228,262 or the GB Patent 2,196,969 is maintained. Applicants argue that it would not be obvious to exclude the leukotoxin required by Potter et al. The examiner agrees. However, the instant claims do not exclude a leukotoxin from being part of the claimed peptide. Note the "comprises" language at instant claim 1, line 1. As long as there are at least two contiguous LHRH sequences joined with a terminus to terminus linkage, other components may be present

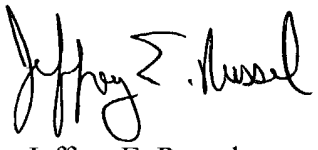
as part of the claimed peptide. Potter et al teach at least two contiguous LHRH sequences joined with a terminus to terminus linkage. See, e.g., claim 5, wherein X can be a peptide linkage or $[GnRH]_n$. In Potter et al, the leukotoxin is then fused to a terminus of this multimer. See, e.g., claims 1 and 19. Potter et al's additional leukotoxin component fused to a terminus of the GnRH multimer is permitted and embraced by Applicants' claim language.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 9, 2004